



2023/0227(COD)

12.3.2024

OPINION

of the Committee on the Environment, Public Health and Food Safety

for the Committee on Agriculture and Rural Development

on the proposal for a regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material)
(COM(2023)0414 – C9-0236/2023 – 2023/0227(COD))

Rapporteur for opinion: Christophe Clergeau

PA_Legam

SHORT JUSTIFICATION

The sustainability and resilience of agriculture and of the entire food chain are largely based on the diversity and quality of seeds and other plant reproductive material (PRM). The main aim of this legislative proposal is to draw up a single regulation with a coherent framework encompassing the provisions hitherto included in 10 separate Directives.

In order to ensure the quality of PRM and consumer confidence, the rules on PRM production and marketing must be based on categorisation and protocols drawn up and monitored by the relevant authorities. Over and above those basic principles, a number of delegated and implementing acts will be drawn up to clarify and adapt the implementation arrangements to the broad diversity of PRM. In line with the principle of proportionality and farmers' right to use their own seeds and other PRM, farmers must not be required to follow the principles set out in this proposal that apply solely to the production of PRM to be placed on the market as PRM rather than for other purposes, such as food. Your rapporteur also believes that farmers should have a derogation for seed and PRM exchanges, including when they receive payment for costs incurred.

Derogations should also be included to facilitate the conservation of certain PRM, recognise the specific characteristics of heterogeneous PRM, adapt the restrictions for sales to non-professional buyers, and recognise the special nature of gene banks and other conservation organisations. Your rapporteur believes, in particular, that heterogeneous material provides crucial pools of genetic diversity for climate change mitigation and that this therefore justifies opening up this category to all species so that they might be included. However, it is necessary, more generally, to exclude from the various derogations PRM consisting of genetically modified organisms or NGT plants.

In order to be registered as a variety, the distinctness, uniformity and stability of the PRM must be verified. In its proposal, the Commission proposes including a complementary technical test of the value for sustainable cultivation and use (VSCU), which should confirm that a variety offers a 'clear improvement' compared to other varieties that are already registered. Your rapporteur believes that the value of a variety depends, first and foremost, on the conditions in which it develops and has been bred: a variety cannot be considered to be sustainable in itself as everything depends on the agricultural production system using it. That is why VSCU should be tested in different production methods, notably where synthetic pesticides are not used, as in organic farming. Moreover, VSCU testing should not result in varieties being excluded if that reduces crop biodiversity. VSCU testing should also be optional for fruits and vegetables because of the costs involved for small and medium-sized seed producers.

Finally, your rapporteur believes that the legislative proposal on PRM requires an amendment of Directive 98/44/EC on the legal protection of biotechnological inventions in order to maintain free access to genetic resources. To avoid destabilising the system of plant variety rights, which ensures fair remuneration for breeders without curbing access to innovation, PRM obtained from new genomic techniques (NGT) should not be patentable. Patents should only be extended to include the organic material derived therefrom. Finally, the scope of compulsory

licensing should be widened in the case of a proven environmental or economic benefit.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Agriculture and Rural Development, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation Recital 5

Text proposed by the Commission

(5) In order to achieve this transition to sustainable food systems, the Union legislation should therefore take account of the need to ensure the adaptability of **the PRM production** to the changing agricultural, horticultural and environmental conditions, to face the challenges of climate change, to protect and restore biodiversity and to meet increasing farmers' and consumers' expectations related to quality and sustainability of PRM.

Amendment

(5) In order to achieve this transition to sustainable food systems, the Union legislation should therefore take account of the need to ensure the adaptability **and diversity** of **PRM** to the changing agricultural, horticultural and environmental conditions, to face the challenges of climate change, to protect and restore biodiversity and to meet increasing farmers' and consumers' expectations related to quality, **resilience** and sustainability of PRM.

Amendment 2

Proposal for a regulation Recital 36 a (new)

Text proposed by the Commission

Amendment

(36 a) The Regulation should strive for the 'One Health Approach' as an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, plants and ecosystems. It recognises that the health of humans, domestic and wild animals, plants, and the wider environment including ecosystems are closely interlinked and inter-dependent;

Amendment 3
Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission

Amendment

(38 a) Heterogeneous material should not consist of a GMO or a category 1 or category 2 NGT plant as defined in Regulation (EU).../...

Amendment 4

Proposal for a regulation
Recital 49

Text proposed by the Commission

Amendment

(49) In order to contribute to the sustainability of agricultural production and serve economic, environmental and broader societal needs, new varieties of all genera or species should show an improvement compared to the other varieties of the same genera or species registered in the same national variety register, concerning certain aspects. Among those aspects are their yield, including yield stability and yield under low input conditions; tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests; tolerance/resistance to abiotic stresses, including adaptation to climate change conditions; more efficient use of natural resources, such as water and nutrients; reduced need for external inputs, such as plant protection products and fertilisers; characteristics that enhance the sustainability of storage, processing and distribution; and quality or nutritional characteristics ('value for sustainable cultivation and use'). For the purpose of deciding on the variety registration and in order to provide sufficient flexibility to register varieties with the most desirable characteristics, those aspects should be

(49) In order to contribute to the sustainability of agricultural production and ***food systems while recognising that sustainability cannot be reduced to a single trait or variety but can only apply to a cultivated system as a whole, and in order to*** serve economic, environmental and broader societal needs, new varieties of all genera or species should show an improvement compared to the other varieties of the same genera or species registered in the same national variety register, concerning certain aspects. Among those aspects are their yield, including yield stability and yield under low input conditions; tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests; tolerance/resistance to abiotic stresses, including adaptation to climate change conditions; more efficient use of natural resources, such as water and nutrients; reduced need for external inputs, such as plant protection products and fertilisers; characteristics that enhance the sustainability of storage, processing and distribution; and quality or nutritional characteristics ('value for sustainable cultivation and use'). For the purpose of

considered for a given variety as a whole.

deciding on the variety registration and in order to provide sufficient flexibility to register varieties with the most desirable characteristics, those aspects should be considered for a given variety as a whole.

Amendment 5
Proposal for a regulation
Recital 64

Text proposed by the Commission

Amendment

(64) Regulation (EU) 2018/848 should be amended to align the definitions of ‘plant reproductive material’ and ‘heterogeneous material’ with the definitions provided for by this Regulation. Moreover, the empowerment for the Commission to adopt specific provisions for the marketing of PRM of organic heterogeneous material should be excluded from Regulation (EU) 2018/848, as all rules concerning the production and marketing of PRM should be set out in this Regulation for reasons of legal clarity.

deleted

Amendment 6
Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

Amendment

This Regulation lays down rules for the production ***and marketing in the Union*** of plant reproductive material (‘PRM’), and in particular requirements for the production of PRM in the field and other sites, categories of material, ***identity*** and quality requirements, certification, labelling, packaging, imports, professional operators and the registration of varieties.

This Regulation lays down rules for the production of plant reproductive material (‘PRM’) ***with a view to its marketing as PRM in the Union***, and in particular requirements for the production of PRM in the field and other sites, categories of material, ***identity*** and quality requirements, certification, labelling, packaging, imports, professional operators and the registration of varieties.

Amendment 7

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 3

Text proposed by the Commission

The requirements concerning production of PRM shall apply only to production with a view to its marketing.

Amendment

The requirements concerning production of PRM shall apply only to production with a view to its marketing **as PRM in the EU**.

Amendment 8
Proposal for a regulation
Article 2 – paragraph 2 – point a

Text proposed by the Commission

(a) to ensure quality and diversity of choice for PRM, and its availability for professional operators and final users;

Amendment

(a) to ensure quality and diversity of choice for PRM, and its availability for professional operators, **farmers** and final users;

Amendment 9
Proposal for a regulation
Article 2 – paragraph 2 – point b

Text proposed by the Commission

(b) to ensure **a equal** conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM;

Amendment

(b) to ensure **appropriate** conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM;

Amendment 10
Proposal for a regulation
Article 2 – paragraph 2 – point d

Text proposed by the Commission

(d) to contribute to conservation and sustainable use of plant genetic resources and agro-biodiversity;

Amendment

(d) to contribute to **the dynamic** conservation and sustainable use of plant genetic resources and agro-biodiversity;

Amendment 11
Proposal for a regulation
Article 2 – paragraph 2 – point e

Text proposed by the Commission

Amendment

(e) to contribute to sustainable **agricultural production**, adapted to current and future projected climatic conditions;

(e) to contribute to sustainable **and productive food systems**, adapted to **diverse climatic and soil conditions**, for current and future projected climatic conditions;

Amendment 12

Proposal for a regulation

Article 2 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) to contribute to food security

(f) to contribute to food security **and food sovereignty**.

Amendment 13

Proposal for a regulation

Article 2 – paragraph 4 – point e

Text proposed by the Commission

Amendment

(e) PRM **used solely** for official testing, breeding, inspections, exhibitions or scientific purposes.

(e) PRM **sold or transferred in any other way, whether free of charge or not**, for official testing, breeding, inspections, exhibitions or scientific purposes, **including for on-farm research and for activities carried out in the framework of the dynamic conservation of genetic resources**;

Amendment 14

Proposal for a regulation

Article 2 – paragraph 4 – point e a (new)

Text proposed by the Commission

Amendment

(e a) PRM produced by farmers for their own use;

Amendment 15

Proposal for a regulation

Article 3 – paragraph 1 – point 29 – point a

Text proposed by the Commission

(a) traditionally grown or locally newly bred under specific local conditions ***in the Union***, and adapted to those conditions; and

Amendment

(a) traditionally grown or locally newly bred ***or developed*** under specific local conditions, and adapted to those conditions ***or the utilisation in a marginal environment or production system***; and

Amendment 16

Proposal for a regulation

Article 3 – paragraph 1 – point 29 – point a a (new)

Text proposed by the Commission

Amendment 17

Proposal for a regulation

Article 3 – paragraph 1 – point 29 – point b

Text proposed by the Commission

(b) characterised by a ***high*** level of genetic and phenotypical diversity between individual reproductive units;

Amendment

(aa) not an F1 hybrid; and

Amendment

(b) ***in the case of seeds, can be*** characterised by a ***certain*** level of genetic and phenotypical diversity between individual reproductive units

Amendment 18

Proposal for a regulation

Article 3 – paragraph 1 – point 35 a (new)

Text proposed by the Commission

Amendment 19

Proposal for a regulation

Article 3 – paragraph 1 – point 35 b (new)

Amendment

(35 a) Plant breeding means activities and practices involved in developing new plant varieties and their selection prior to application for registration;

Text proposed by the Commission

Amendment

(35 b) ‘dynamic conservation of plant genetic resources’ means activities carried out by gene banks, community seed banks and other organisations and networks, as well as their members and individual seed savers, implying transfers of PRM in both formal and informal ways, whether or not for consideration and seeking to contribute to the long-term conservation and enrichment of plant genetic diversity.

Amendment 20

Proposal for a regulation

Article 5 – paragraph 1 – point e

Text proposed by the Commission

Amendment

(e) as ***seed*** exchanged ***in kind*** between farmers in accordance with Article 30;

(e) as ***PRM*** exchanged between farmers in accordance with Article 30;

Amendment 21

Proposal for a regulation

Article 6 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) as ***seed*** exchanged ***in kind*** between farmers in accordance with Article 30;

(d) as ***PRM*** exchanged between farmers in accordance with Article 30;

Amendment 22

Proposal for a regulation

Article 22 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) it is not covered by an intellectual property right limiting its use for conservation purposes.

Amendment 23

Proposal for a regulation

Article 22 – paragraph 1 – subparagraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) it does not consist of a GMO or a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) or of a category 1 or 2 NGT plant as defined in Article 3(8) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...).

Amendment 24
Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission

Amendment

1. By way of derogation from Article 20, PRM belonging to a conservation variety registered in a national variety register referred to in Article 44(1), point (b), may be produced and marketed in the Union as standard seed or material, if it complies with all the requirements concerning standard seed and material for the respective species, as referred to in Article 8.

1. By way of derogation from Article 20, PRM ***of all genera or species listed in Annex I*** belonging to a conservation variety registered in a national variety register referred to in Article 44(1), point (b), may be produced and marketed in the Union as standard seed or material, if it complies with all the requirements concerning standard seed and material for the respective species, as referred to in Article 8.

Amendment 25
Proposal for a regulation
Article 26 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. A variety of conservation, its parts and/or its genetic components may not be covered by an intellectual property right limiting its use for conservation, research, breeding and/or training, including on-farm participatory research and breeding.

Amendment 26
Proposal for a regulation
Article 27 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Those amendments shall be **adopted** in order to adapt to the development of the respective technical and scientific evidence, and the international standards, and to follow up on the experience gained by the application of this Article concerning all **or certain genera or species only**.

Amendment 27
Proposal for a regulation
Article 27 – paragraph 4

Text proposed by the Commission

4. Any professional operator producing and/or intending to market PRM of heterogeneous material shall submit a notification to the competent authority prior to marketing. If no further information is requested by the national competent authority within **a time determined by the competent authority**, the PRM of heterogeneous material may be marketed.

Amendment 28
Proposal for a regulation
Article 27 – paragraph 7 – subparagraph 1

Text proposed by the Commission

Heterogeneous material as notified pursuant to paragraph 1, shall be registered by the competent authorities in a dedicated register ('heterogeneous material register').

Amendment 29
Proposal for a regulation
Article 29 – title

Amendment

Those amendments shall be **developed in consultation with respective multi actor stakeholders involved in heterogeneous material** in order to adapt to the development of the respective technical and scientific evidence, and the international standards, and to follow up on the experience gained by the application of this Article concerning all species.

Amendment

4. Any professional operator producing and/or intending to market PRM of heterogeneous material shall submit a notification to the competent authority prior to marketing. If no further information is requested by the national competent authority within **three months**, the PRM of heterogeneous material may be marketed.

Amendment

Heterogeneous material as notified pursuant to paragraph 1, shall be registered by the competent authorities in a dedicated register ('heterogeneous material register').
Registration shall be free of charge.

Text proposed by the Commission

Amendment

PRM marketed *to* and between *gene banks*, organisations and networks

PRM marketed *by, to, within* and between organisations and networks *dedicated to the dynamic conservation and sustainable use of plant genetic resources*

Amendment 30
Proposal for a regulation
Article 29 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

By way of derogation from Articles 5 to 25, PRM may be marketed *to*, or between, *gene banks*, organisations and networks *with a statutory objective, or an objective official notified to the competent authority, to conserve* plant genetic resources, whereby any of the activities are carried out for non-profit purposes.

By way of derogation from Articles 5 to 25, PRM may be marketed *by, to, within*, or between organisations and networks, *including farmers, dedicated to the dynamic conservation and sustainable use of plant genetic resources* whereby any of the activities are carried out for non-profit purposes.

Amendment 31
Proposal for a regulation
Article 29 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

It can be marketed as well from those *gene banks*, organisations and networks to persons who carry out conservation of that PRM as final consumers, *for non-profit* purposes.

It can be marketed as well from those *conservation organisations and networks or their members* to persons who carry out *dynamic* conservation of that PRM as final consumers, *or for professional farming* purposes.

Amendment 32
Proposal for a regulation
Article 29 – paragraph 1 – subparagraph 3 – introductory part

Text proposed by the Commission

Amendment

In the cases provided for in the first and the second subparagraphs, *PRM* shall fulfil the *following requirements*:

In the cases provided for in the first and the second subparagraphs, *conservation organisations and networks* shall *not* fulfil the *obligations under Article 41 to 43, and PRM shall be listed in a register kept by*

those conservation organisations and networks with a basic description of that PRM.

Amendment 33

Proposal for a regulation

Article 29 – paragraph 1 – subparagraph 3 – point a

Text proposed by the Commission

Amendment

(a) be listed in a register kept by those gene banks, organisations and networks with an appropriate description of that PRM; *deleted*

Amendment 34

Proposal for a regulation

Article 29 – paragraph 1 – subparagraph 3 – point b

Text proposed by the Commission

Amendment

(b) be conserved by those gene banks, organisations and networks, and samples of that PRM be made available by them to the competent authorities upon request; and *deleted*

Amendment 35

Proposal for a regulation

Article 29 – paragraph 1 – subparagraph 3 – point c

Text proposed by the Commission

Amendment

(c) be practically free from quality pests and any defects likely to impair its quality as a reproductive material, and have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, have satisfactory germination capacity. *deleted*

Amendment 36

Proposal for a regulation

Article 29 – paragraph 2

Text proposed by the Commission

Amendment

2. ***The gene banks, organisations and networks shall notify the competent authority of the use of the derogation referred to in paragraph 1 and the species concerned.*** ***deleted***

Amendment 37
Proposal for a regulation
Article 30 – title

Text proposed by the Commission

Amendment

Seed exchanged ***in kind*** between farmers

PRM exchanged between farmers

Amendment 38
Proposal for a regulation
Article 30 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. By way of derogation from Articles 5 - 25, farmers may exchange ***seeds*** in kind, if such ***seeds fulfill*** all of the following conditions:

1. By way of derogation from Articles 5 - 25, farmers may exchange ***PRM*** in kind ***or for monetary compensation covering direct costs incurred***, if such ***PRM fulfils*** all of the following conditions:

Amendment 39
Proposal for a regulation
Article 30 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) are not subject to a service contract conducted by the respective farmer with a professional operator performing ***seed*** production; and

(3) are not subject to a service contract ***for multiplication*** conducted by the respective farmer with a professional operator performing ***PRM*** production; and

Amendment 40
Proposal for a regulation
Article 30 – paragraph 1 – point 4

Text proposed by the Commission

(4) the **seed** is used for dynamic management of farmer's own **seed** for the purpose of contributing to agro-diversity.

Amendment

(4) the **PRM** is used for dynamic management of farmer's own **PRM** for the purpose of contributing to agro-diversity.

Amendment 41
Proposal for a regulation
Article 30 – paragraph 2 – introductory part

Text proposed by the Commission

2. Such **seeds** shall fulfil all of the following requirements:

Amendment

2. Such **PRM** shall fulfil all of the following requirements:

Amendment 42
Proposal for a regulation
Article 30 – paragraph 2 – point a

Text proposed by the Commission

(a) not to belong to a to variety for which plant variety rights have been granted in accordance with Regulation (EU) 2100/94;

Amendment

(a) not to belong to a to variety for which plant variety rights have been granted in accordance with Regulation (EU) 2100/94 **and where the right is still in force**;

Amendment 43
Proposal for a regulation
Article 30 – paragraph 2 – point b

Text proposed by the Commission

(b) to be limited to small quantities, defined by the competent authorities for specific species per year **and per farmer**, without using commercial intermediaries or public offer of marketing; and

Amendment

(b) to be limited to small quantities defined by the competent authorities **sufficient to meet the own needs of a farmer** for specific species per year, without using commercial intermediaries or public offer of marketing; and

Amendment 44
Proposal for a regulation
Article 30 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) to be practically free from quality pests and any defects likely to impact their quality as **seeds, and shall have satisfactory germination capacity.**

(c) to be practically free from quality pests and any defects likely to impact their quality as **PRM.**

Amendment 45
Proposal for a regulation
Article 30 – paragraph 3

Text proposed by the Commission

Amendment

3. Member States shall annually notify to the Commission and the other Member States the amounts per species defined in accordance with paragraph 2, point (b).

deleted

Amendment 46
Proposal for a regulation
Article 32 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

This derogation shall not apply to PRM consisting of a genetically modified organism within the meaning of Directive 2001/18/EC or PRM consisting of an NGT plant within the meaning of Regulation (EU).../...

Amendment 47
Proposal for a regulation
Article 33 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. This exceptional authorisation shall not apply to PRM consisting of a genetically modified organism within the meaning of Directive 2001/18/EC or PRM consisting of an NGT plant within the meaning of Regulation (EU).../...

Amendment 48

Proposal for a regulation

Article 35 – paragraph 1 – point c

Text proposed by the Commission

(c) the requirements set out in paragraphs 2 to 5 are fulfilled.

Amendment

(c) the requirements set out in paragraphs 2 to **5a** are fulfilled.

Amendment 49

Proposal for a regulation

Article 35 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. This derogation shall not apply to PRM consisting of a genetically modified organism within the meaning of Directive 2001/18/EC or PRM consisting of an NGT plant within the meaning of Regulation (EU).../...

Amendment 50

Proposal for a regulation

Article 37 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Where the production or marketing of PRM **is likely to** constitute a serious risk to human, animal or plant health, environment or cultivation of other species, and such risk cannot be contained satisfactorily by means of measures taken by the Member State concerned, the Commission shall take, without delay, by means of implementing acts, any appropriate interim emergency measures. Such measures shall be limited in time. They may include provisions restricting or prohibiting the marketing of the PRM concerned or laying down appropriate conditions for its production or marketing,

Amendment

Where **there are reasonable grounds to suspect that** the production or marketing of PRM **could** constitute a serious risk to human, animal or plant health, environment or cultivation of other species, and such risk cannot be contained satisfactorily by means of measures taken by the Member State concerned, the Commission shall take, without delay, by means of implementing acts, any appropriate interim emergency measures. Such measures shall be limited in time. They may include provisions restricting or prohibiting the marketing of the PRM concerned or laying down appropriate

depending on the gravity of the situation.

conditions for its production or marketing,
depending on the gravity of the situation.

Amendment 51

Proposal for a regulation

Article 37 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

By means of derogation from the first subparagraph, in case of lack of compliance with refuge requirements or with other requirements imposed on cultivation of varieties containing or consisting of genetically modified organisms, the measures restricting or prohibiting the marketing of the PRM concerned shall be put in place until full compliance is restored.

Amendment 52

Proposal for a regulation

Article 41 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The activities referred to in Articles 28, 29 and 30 shall not be subject to the provisions of this article.

Amendment 53

Proposal for a regulation

Article 42 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The activities referred to in Articles 28, 29 and 30 shall not be subject to the provisions of this article.

Amendment 54

Proposal for a regulation

Article 47 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) where the varieties are tolerant to herbicides, they are subject to cultivation and monitoring conditions for the production of PRM and for any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for registration, to avoid the development of herbicide resistance in weeds due to their use;

Justification

The ENVI committee doesn't have any competence over the point f) despite the fact that it is about GMO crops. the text is copied and "the monitoring conditions", as also normally imposed on cultivated GMO crop to respective properties of which pests can develop resistance, is added, as it is also considered relevant.

Amendment 55

Proposal for a regulation

Article 47 – paragraph 1 – subparagraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) where the varieties have particular characteristics other than the ones referred to in point (ca) that may lead to undesirable agronomic effects, they are subject to cultivation and monitoring conditions for the production of PRM and any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for their registration, to avoid those particular undesirable agronomic effects, such as the development of resistance of pests to the respective varieties or undesirable effects on pollinators or on wild growing plants of the same genus as the respective variety.

Justification

The ENVI committee doesn't have any competence over the point g) despite the fact that it is about GMO crops. the text is copied and "the monitoring conditions", as also normally imposed on cultivated GMO crop to respective properties of which pests can develop resistance, is added, as it is also considered relevant. also "wild growing plants" is added, as e.g. the cultivated maize MON810 in the EU has a wild relative present, teosinte, and also their co-occurrence is being monitored.

Amendment 56 **Proposal for a regulation** **Article 52 – title**

Text proposed by the Commission

Value for sustainable cultivation and use

Amendment

Value for sustainable **and productive** cultivation and use

Amendment 57 **Proposal for a regulation** **Article 52 – paragraph 1 – subparagraph 1**

Text proposed by the Commission

For the purposes of Article 47(1), point (c), the value of a variety for sustainable cultivation and use of a variety shall be considered as satisfactory if, compared to other varieties of the same species registered in the national variety register of the respective Member State, its characteristics, taken as a whole, offer a clear improvement for the sustainable cultivation and the uses which can be made of the crops, other plants or the products derived therefrom.

Amendment

For the purposes of Article 47(1), point (c), the value of a variety for sustainable **and productive** cultivation and use of a variety shall be considered as satisfactory if, compared to other varieties of the same species registered in the national variety register of the respective Member State, its characteristics, taken as a whole, **are superior and** offer a clear improvement, **in at least one of the existing agricultural production systems**, for the sustainable **and productive** cultivation and the uses which can be made of the crops, other plants or the products derived therefrom.

Amendment 58 **Proposal for a regulation** **Article 52 – paragraph 1 – subparagraph 2 – introductory part**

Text proposed by the Commission

Amendment

The characteristics referred to in the first subparagraph *are* the following, as appropriate for the species, regions, agro-ecological conditions and uses concerned:

The characteristics referred to in the first subparagraph *shall be tested in different agricultural production systems, inter alia conventional, organic, agro-ecological, regenerative, conservation, integrated management using minimal fertilisers and irrigation. The characteristics may encompass* the following as appropriate for the species, regions, agro-ecological conditions and uses concerned:

Amendment 59

Proposal for a regulation

Article 52 – paragraph 1 – subparagraph 2 – point f

Text proposed by the Commission

Amendment

(f) characteristics that *enhance the sustainability of* storage, *processing and* distribution;

(f) characteristics that *strengthen sustainability and productivity across the whole agrifood value chain, including harvest, storage, distribution and processing or other relevant characteristics;*

Amendment 60

Proposal for a regulation

Article 52 – paragraph 1 – subparagraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) preservation of traditional and cultural heritage.

Amendment 61

Proposal for a regulation

Article 52 – paragraph 1 – subparagraph 2 – point g b (new)

Text proposed by the Commission

Amendment

(g b) would strengthen the economic, ecological and social sustainability of a regional area, impacting positively on the conservation and preservation of the traditional landscape;

Amendment 62
Proposal for a regulation
Article 52 – paragraph 1 – subparagraph 2 – point g c (new)

Text proposed by the Commission

Amendment

(g c) enhancement of the sustainability of the agricultural production systems in an ecosystem-based approach that takes into account all interactions with the environment concerned.

Amendment 63
Proposal for a regulation
Article 52 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The examination of the value for sustainable and productive cultivation and use shall remain voluntary for species listed in Parts B and C of Annex I.

Amendment 64
Proposal for a regulation
Article 52 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. The examination of the value for sustainable and productive cultivation and use must not lead to the exclusion of varieties that would reduce the diversity of the species cultivated.

Amendment 65
Proposal for a regulation
Article 52 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

For the purposes of registration of organic varieties suitable for organic production as defined in Article 3(19) of Regulation (EU) 2018/848, the examination of the value for sustainable

In order to obtain information about the resilience of the PRM, the examination of the value for sustainable and productive cultivation and use *may also* be conducted under low-input conditions and with only

cultivation and use *shall* be conducted under organic conditions, in accordance with *that* Regulation, and in particular Article 5, points (d), (e), (f) and (g), and Article 12 *thereof* and Part I of Annex II *to that Regulation*.

the absolutely necessary for the completion of the testing treatments with pesticides and other external inputs, or under organic conditions in accordance with Regulation (EU) 2018/848, and in particular Article 5, points (d), (e), (f) and (g), and Article 12 and Part I of Annex II.

Amendment 66
Proposal for a regulation
Article 52 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Where competent authorities are not able to carry out an examination under organic conditions, or the examination of certain characteristics, including disease susceptibility, testing may be carried out under low-input conditions and with only the absolutely necessary *for the completion of the testing* treatments with pesticides and other external inputs.

Amendment

Where competent authorities are not able to carry out an examination under organic conditions, or the examination of certain characteristics, including disease susceptibility, testing may be carried out *by professional operators involved in organic farming or by organic farmers under in-conversion or* low-input conditions and with only the absolutely necessary treatments with pesticides and other external inputs *for the completion of the examination. Where applicable, Member States must report annually to the Commission on the reasons implying those treatments as well as on the commitments taken to enable this transition in the future.*

Amendment 67
Proposal for a regulation
Article 52 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. *Competent authorities shall consider to include testing of conventional seed under low input conditions, organic in-conversion, or organic conditions.*

Amendment 68
Proposal for a regulation

Article 53 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The competent authority shall accept or reject the registration of a conservation variety, after checking its compliance with paragraph 1.

Amendment

The competent authority shall accept or reject the registration of a conservation variety, after checking its compliance with paragraph 1. ***It shall inform the applicant of its decision, stating, where applicable, the grounds for refusal.***

Amendment 69

Proposal for a regulation

Article 54 – paragraph 1 – point c – paragraph 1 – point i

Text proposed by the Commission

(i) under which another variety of the same or of a closely related species is entered in a national variety register or in the Union variety register; or

Amendment

(i) under which another variety of the same or of a closely related species is entered in a national variety register or in the Union variety register, ***in a commercial catalogue of a professional operator, or in documentation that is publicly available or has been submitted to the competent authority by a natural or legal person involved in the dynamic conservation or sustainable use of plant genetic resources and crop biodiversity;*** or

Amendment 70

Proposal for a regulation

Article 56 – paragraph 1 – point j

Text proposed by the Commission

(j) where the variety contains or consists of a genetically modified organism, evidence that the genetically modified organism in question is authorised for cultivation in the Union, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, or, where applicable, in the respective Member State in accordance with Article 26b of Directive 2001/18/EC;;

Amendment

(j) where the variety contains or consists of a genetically modified organism, evidence that the genetically modified organism in question is authorised for cultivation in the Union, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, or, where applicable, in the respective Member State in accordance with Article 26b of Directive 2001/18/EC, ***and the evidence of compliance with the cultivation and***

monitoring requirements in the given growing season;

Amendment 71

Proposal for a regulation

Article 56 – paragraph 1 – point l a (new)

Text proposed by the Commission

Amendment

(la) the existence of intellectual property rights other than granted plant variety right on the variety as a whole or its components;

Amendment 72

Proposal for a regulation

Article 61 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the examination does not replace the risk assessment required to apply for marketing authorisation under Directive 2001/18/EC on genetically modified organisms or under Regulation (EU) .../... on plants obtained by certain new genomic techniques.

Amendment 73

Proposal for a regulation

Article 69 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

However, that period of registration shall be 30 years for varieties of species of fruit plants and vine propagating material, as listed respectively in Parts C and D of Annex I.

However, that period of registration shall be 30 years for **conservation varieties and** varieties of species of fruit plants and vine propagating material, as listed respectively in Parts C and D of Annex I.

Amendment 74

Proposal for a regulation

Article 77 a (new)

Text proposed by the Commission

Amendment

Article 77a

Commission report

No later than the entry into force of this Regulation, the Commission shall submit a report to the European Parliament and to the European Council assessing the adequacy of the provisions introduced by this Regulation and the resources available to the competent authorities to implement them. In its assessment, the Commission shall pay particular attention to the VSCU technical test as the derogation provided for in Article 61 of this Regulation should be used with great care in order to ensure the credibility of VSCU testing. Where appropriate, the Commission shall put forward proposals, including budgetary proposals, to balance the needs and resources of the competent authorities.

Amendment 75

Proposal for a regulation

Article 80 – paragraph 1 – point 1

Regulation (EU) 2017/625

Article 1, para 2, points (ka) and (kb) (new)

Text proposed by the Commission

Amendment

(k) production and marketing of plant reproductive material.;

(k) production and marketing of plant reproductive material.;

‘(ka) the cultivation of varieties tolerant to herbicides;

(kb) cultivation of varieties with particular characteristics that may lead to undesirable agronomic effects’.

(This amendment applies throughout the text. Adopting it will necessitate

corresponding changes throughout.)

(Regulation (EU) 2017/625)

Justification

The gives competent authorities the competence to control implementation of cultivation conditions prescribed for herbicide tolerant varieties and other varieties with particular characteristics that may lead to undesirable agronomic effects, as per Article 47. If authorities have no competence to control the cultivation of such varieties, the entire benefit and efficiency of this measure on herbicide tolerant varieties and of varieties with particular characteristics that may lead to undesirable agronomic effects, should these be defined at a later date, would be lost.

Amendment 76

Proposal for a regulation

Article 81

Regulation (EU) 2018/848

Article 3, 13 and Annex II

Text proposed by the Commission

Amendment

Article 81

deleted

Amendment of Regulation (EU) 2018/848

Regulation (EU) 2018/848 is amended as follows:

(1) Article 3 is amended as follows:

(a) point (17) is replaced by the following:

‘(17)

‘plant reproductive material’ means plant reproductive material as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and Council(*)+;’;

(*) Regulation (EU) .../... of the European Parliament and of the Council (OJ ..., p...). [footnote that will be in that regulation goes here]

[+ OJ: Please insert in the text the number of this Regulation and insert the number, date, title and OJ reference of this Regulation in the footnote.]

(18)

‘organic heterogeneous material’ means heterogeneous material as defined in Article 3(27) of Regulation (EU) .../...(*)⁺⁺, produced in accordance with this Regulation;’

(*) Regulation (EU) .../... of the European Parliament and of the Council (OJ ..., p...). [footnote that will be in that regulation goes here]

[⁺⁺ OJ: Please insert in the text the number of this Regulation.]

(3) The second paragraph of Point 1.8.4. of Part I of Annex II to Regulation (EU) 2018/848 is replaced by the following: “ All multiplication practices, except plant tissue cultures, cell cultures, germplasm, meristems, chimaeric clones, micro-propagated material, shall be carried out under certified organic management”.

Amendment 77

Proposal for a regulation Article 81 a (new)

Text proposed by the Commission

Amendment

Article 81a

Amendment of Directive 98/44/EC

Directive 98/44/EC is amended as follows:

Amendment 78

Proposal for a regulation Article 81 b (new)

Text proposed by the Commission

Amendment

(1) In Article 4, the following paragraphs 4 and 5 are inserted:

‘4. By way of derogation from paragraphs 1, 2 and 3, NGT plants, plant

material and parts thereof, and the genetic information they contain, shall not be patentable.

5. By way of derogation from paragraphs 1, 2 and 3, plants, plant material and parts thereof, and the genetic information they contain, which have been obtained using techniques excluded from the scope of Directive 2001/18/EC as listed in Annex 1B thereto, shall not be patentable.'

Amendment 79
Proposal for a regulation
Annex VI – Part B – point 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) Heterogeneous material must not be derived from parental material covered by patents nor be protected by patents.

Amendment 80

Proposal for a regulation
Annex VII – paragraph 1 – point t a (new)

Text proposed by the Commission

Amendment

(ta) whether there are any intellectual property rights covering the variety as a whole or its genetic components or the genetic information contained therein, including, where applicable, the number of any relevant patent(s);

Justification

To provide transparency to users, the information provided on a variety in the EU and national registers should include information on intellectual property rights, especially patents that may have been granted on parts of the registered variety, such as genetic sequences or traits. This is crucial information for all follow-on users, whether farmers, breeders, seed conservation

Amendment 81

Proposal for a regulation

Annex VII – paragraph 1 – point t b (new)

Text proposed by the Commission

Amendment

(tb) disclose which breeding techniques have been applied for the development of the plant (e.g., cell fusion, genetic engineering, chemical or irradiation mutation breeding, microspore culture, etc.)

**ANNEX: LIST OF ENTITIES OR PERSONS
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

List of entities or persons from whom the rapporteur has received input
IFOAM
Copa-Cogeca
Via Campesina
Limagrain
Arche Noah
INRAE
Brot für die Welt
SEMAE
Euroseeds

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material)
References	COM(2023)0414 – C9-0236/2023 – 2023/0227(COD)
Committee responsible Date announced in plenary	AGRI 19.10.2023
Opinion by Date announced in plenary	ENVI 19.10.2023
Associated committees - date announced in plenary	19.10.2023
Rapporteur for the opinion Date appointed	Christophe Clergeau 24.10.2023
Discussed in committee	11.1.2024
Date adopted	11.3.2024
Result of final vote	+: 44 –: 1 0: 39
Members present for the final vote	Catherine Amalric, Mathilde Androuët, Maria Arena, Margrete Auken, Marek Paweł Balt, Traian Băsescu, Aurélia Beigneux, Sergio Berlato, Alexander Bernhuber, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Nathalie Colin-Oesterlé, Maria Angela Danzi, Christian Doleschal, Bas Eickhout, Pietro Fiocchi, Heléne Fritzon, Andreas Glück, Catherine Griset, Martin Hojsík, Pär Holmgren, Jan Huitema, Adam Jarubas, Karin Karlsbro, Ewa Kopacz, Peter Liese, Javi López, César Luena, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Lydie Massard, Liudas Mažylis, Tilly Metz, Dolors Montserrat, Ville Niinistö, Ljudmila Novak, Henk Jan Ormel, Grace O’Sullivan, Jutta Paulus, Francesca Peppucci, Stanislav Polčák, Jessica Polfjård, María Soraya Rodríguez Ramos, Sándor Rónai, Maria Veronica Rossi, Laurence Sailliet, Silvia Sardone, Günther Sidl, Ivan Vilibor Sinčić, Nils Torvalds, Edina Tóth, Anders Vistisen, Pernille Weiss, Emma Wiesner, Michal Wieszik, Tiemo Wölken, Stefania Zambelli
Substitutes present for the final vote	Matteo Adinolfi, João Albuquerque, Stefan Berger, Biljana Borzan, Mercedes Bresso, Milan Brglez, Martin Buschmann, Cristian-Silviu Buşoi, Catherine Chabaud, Asger Christensen, Dacian Cioloş, Christophe Clergeau, Deirdre Clune, Gilbert Collard, Antoni Comín i Oliveres, Rosanna Conte, Beatrice Covassi, Gianantonio Da Re, Ivan David, Margarita de la Pisa Carrión, Anna Deparnay-Grunenberg, Estrella Durá Ferrandis, Giuseppe Ferrandino, Laura Ferrara, Cindy Franssen, Claudia Gamon, Matteo Gazzini, Jens Gieseke, Sunčana Glavak, Nicolás González Casares, Robert Hajšel, Martin Häusling, Romana Jerković, Irena Joveva, Radan Kanev, Karol Karski, Billy Kelleher, Ska Keller, Martine Kemp, Ondřej Knotek, Kateřina

	Konečná, Stelios Kypouropoulos, Danilo Oscar Lancini, Norbert Lins, Fulvio Martusciello, Marisa Matias, Sara Matthieu, Radka Maxová, Dace Melbārde, Nuno Melo, Marlene Mortler, Dan-Ștefan Motreanu, Ulrike Müller, Dan Nica, Max Orville, Demetris Papadakis, Aldo Patriciello, Piernicola Pedicini, Lídia Pereira, Sirpa Pietikäinen, João Pimenta Lopes, Rovana Plumb, Manuela Ripa, Robert Roos, Marcos Ros Sempere, Massimiliano Salini, Christel Schaldemose, Andrey Slabakov, Vincenzo Sofo, Tomislav Sokol, Susana Solís Pérez, Nicolae Ștefănuță, Annalisa Tardino, Hermann Tertsch, François Thiollet, Róza Thun und Hohenstein, Grzegorz Tobiszowski, Marie Toussaint, István Ujhelyi, Inese Vaidere, Idoia Villanueva Ruiz, Sarah Wiener, Jadwiga Wiśniewska
Substitutes under Rule 209(7) present for the final vote	Marie Dauchy, Pascal Durand, Sylvie Guillaume, Alessandro Panza, Rob Rooker, Dorien Rookmaker, Bert-Jan Ruissen, Evžen Tošenovský

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

44	+
ECR	Dorien Rookmaker
ID	Mathilde Androuët, Aurélia Beigneux, Marie Dauchy, Catherine Griset, Anders Vistisen
NI	Maria Angela Danzi
Renew	Pascal Canfin, Martin Hojsik, María Soraya Rodríguez Ramos, Róza Thun und Hohenstein, Michal Wiezik
S&D	João Albuquerque, Maria Arena, Marek Paweł Balt, Milan Brglez, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Christophe Clergeau, Beatrice Covassi, Pascal Durand, Sylvie Guillaume, Javi López, César Luena, Sándor Rónai, Günther Sidl, Tiemo Wölken
The Left	Malin Björk, Anja Hazekamp, Marina Mesure, Idoia Villanueva Ruiz, Nikolaj Villumsen, Mick Wallace
Verts/ALE	Margrete Auken, Bas Eickhout, Pär Holmgren, Ska Keller, Lydie Massard, Tilly Metz, Ville Niinistö, Grace O'Sullivan, Jutta Paulus, Manuela Ripa

1	-
ECR	Pietro Fiocchi

39	0
ECR	Sergio Berlato, Rob Rooken, Robert Roos, Bert-Jan Ruissen, Evžen Tošenovský
ID	Alessandro Panza, Maria Veronica Rossi, Silvia Sardone
NI	Ivan Vilibor Sinčić, Edina Tóth
PPE	Traian Băsescu, Alexander Bernhuber, Cristian-Silviu Buşoi, Nathalie Colin-Oesterlé, Christian Doleschal, Adam Jarubas, Ewa Kopacz, Peter Liese, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Liudas Mažylis, Dolors Montserrat, Marlene Mortler, Ljudmila Novak, Henk Jan Ormel, Francesca Peppucci, Stanislav Polčák, Jessica Polfjård, Laurence Sailliet, Pernille Weiss, Stefania Zambelli
Renew	Catherine Amalric, Andreas Glück, Jan Huitema, Karin Karlsbro, Ondřej Knotek, Nils Torvalds, Emma Wiesner
S&D	Heléne Fritzon

Key to symbols:

+ : in favour

- : against

0 : abstention